UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,359	02/26/2004	James H. Brauker	DEXCOM.037A	5145

20995 7590 11/27/2006

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SMITH, PAUL B	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,359	BRAUKER ET AL.	
	Examiner	Art Unit	
	Paul B. Smith	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/11/2005 7/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/11/2005 and 7/21/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 15-17, 22-25, 26-29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord *et al.* ('186).

4. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

5. It appears that Lord *et al.* reasonably discloses every element of claims 15-17, 22-25, 26-29 and 33.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord *et al.* ('186) in view of Connelly *et al.* ('229).

9. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver

medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

10. Lord *et al.* fails to disclose a medicament delivery device comprising a syringe or pen injector.

11. Connelly *et al.* teaches that it is common in the art of insulin therapy to use either a syringe or pen to deliver insulin to a patient. (See Column 1 Lines 34-38)

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lord *et al.* with the teachings of Connelly *et al.* to provide either a syringe or pen as a medicament delivery device.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord *et al.* ('186) in view of Mitragotri *et al* ('599).

14. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is

detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

15. Lord *et al.* fails to disclose a medicament delivery device comprising one or more transdermal patches.

16. Mitragotri *et al.* teaches the use of a transdermal patch to administer insulin to a diabetic patient. (See Column 5 Lines 35-45)

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lord *et al.* with the teachings of Mitragotri *et al.* to provide a medicament delivery device comprising a transdermal patch.

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord *et al.* ('186) in view of Mullins ('533).

19. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is

detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

20. Lord *et al.* fails to disclose a medicament delivery device comprising a spray or inhaler.

21. Mullins teaches an inhaler that sprays insulin for treating diabetes. (See Column 7 Lines 25-35)

22. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Lord *et al.* with the teachings of Mullins to provide a medicament delivery device comprising an inhaler.

23. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord *et al.* ('186) in view of Yamaguchi *et al.* ('516).

24. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is

detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

25. Lord *et al.* fails to disclose a glucose sensor comprising an enzyme membrane.

26. Yamaguchi *et al.* teaches an enzyme sensor that is able to sense glucose level in a patient. (See Abstract)

27. At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the disclosure of Lord *et al.* with the teachings of Yamaguchi *et al.* to provide a glucose sensor comprising an enzyme membrane.

28. Claims 31-32, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord *et al.* ('186) in view of Mann *et al.* ('743).

29. Lord *et al.* discloses an infusion system comprising an implantable glucose sensor (16), a receiver (28) and a medicament delivery device (14). The medicament delivery device comprises an implantable infusion pump. (See Figure 1) The infusion pump may be programmed to deliver medicine or maybe manually activated to deliver medicine. (Column 4 Lines 5-10) The receiver is disclosed as a wristband that is detachably connected to said patient. (See Figure 1) Said receiver communicates with said infusion pump and said sensor via a wireless connection. (Column 3 Lines 49-67)

30. Lord *et al.* fails to specifically disclose a receiver with a microprocessor and programming.

31. Mann *et al.* teaches an infusion device comprising a microprocessor configured to facilitate remote programming. (See Column 2 Lines 34-46)

32. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Lord *et al.* with the teachings of Mann *et al.* to provide a receiver with a microprocessor.

Conclusion

33. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. U.S. Patent 6,248,067 to Causey, III *et al.*

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith
Examiner
Art Unit 3763

PBS
November 20, 2006